# FOOD SAFETY AND INSPECTION SERVICE

# 2003 FSIS NATIONAL RESIDUE PROGRAM DATA

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#### **PREFACE**

The "2003 Food Safety and Inspection Service (FSIS) National Residue Program Data" publication, (Red Book) presents the calendar year chemical residue testing results. [For those reading this electronically, this document has been commonly known as the "Red Book" because the covers of the printed versions are red.] The document explains the sampling plans and presents the National Residue Program (NRP) data. In addition, the following appendices are included for the convenience of the reader: Appendix I, *U.S. Residue Limits for Veterinary Drugs, Food Additives and Unavoidable Contaminants in Meat, Poultry, and Egg Products;* Appendix II, *U.S. Residue Limits for Pesticides in Meat, Poultry, and Egg Products;* Appendix III, *Analytical Methods, 2003 FSIS National Residue Program;* and Appendix IV, *Statistical Table*.

#### **CONTACTS AND COMMENTS**

The Residue Branch (RB), Zoonotic Diseases and Residue Surveillance Division (ZDRSD), Office of Public Health Science, FSIS, USDA, coordinated this effort and is responsible for the publication of this material. Questions about FSIS NRP should be directed to the USDA, FSIS, ZDRSD, 343 Aerospace Center, 1400 Independence Avenue, SW, Washington D.C. 20250-3700, telephone (202) 690-2683, and fax (202) 690-6565.

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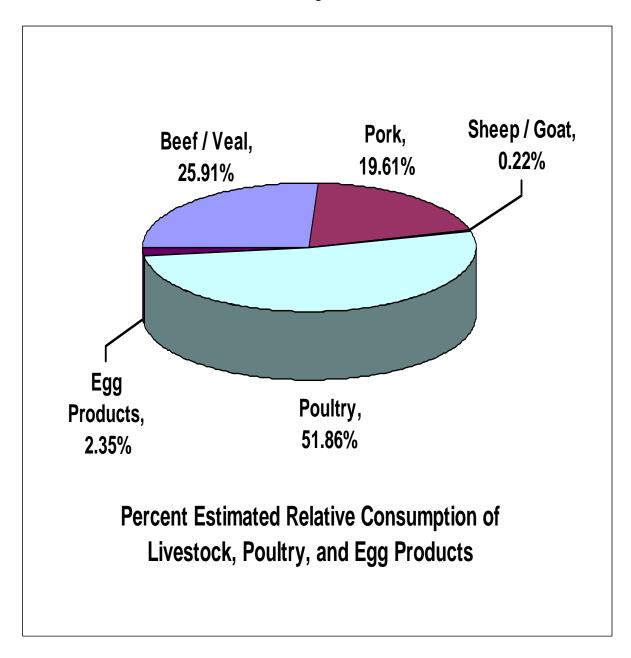
# ESTIMATED LIVESTOCK, POULTRY, AND EGG PRODUCT CONSUMPTION DATA

Table 1 and Chart 1, 2003 Consumption Data, presents the number of head slaughtered or eggs processed, pounds per animal dressed weight, total pounds dressed weight, and the percent estimated relative consumption of domestic and exported product for each production class.

Table 1 2003 Consumption Data

Production Class	Number of Head Slaughtered	Pounds per Animal (dressed weight)	Total Pounds (dressed weight)	Percent Estimated Relative Consumption
Bulls	629,000	904	568,616,000	0.562
Beef cows	3,163,000	590	1,866,170,000	1.844
Dairy cows	2,860,000	590	1,687,400,000	1.667
Heifers	11,078,200	732	8,109,242,400	8.013
Steers	17,177,000	803	13,793,131,000	13.629
Bob veal	382,692	75	28,701,900	0.028
Formula-fed veal	561,716	245	137,620,420	0.136
Non-formula-fed veal	26,036	350	9,112,600	0.009
Heavy calves	42,776	400	17,110,400	0.017
Subtotal, Cattle	35,920,420		26,217,104,720	25.905
Market hogs	96,242,000	195	18,767,190,000	18.544
Roaster pigs	160,000	70	11,200,000	0.011
Boars/Stags	241,200	241	58,129,200	0.057
Sows	3,215,300	315	1,012,819,500	1.001
Subtotal, Swine	99,858,500		19,849,338,700	19.613
Lambs	2,662,000	68	181,016,000	0.179
Sheep	143,000	66	9,438,000	0.009
Goats	646,954	50	32,347,700	0.032
Subtotal, Sheep/Goats	3,451,954		222,801,700	0.220
Horses	50,062	500	25,031,000	0.025
Bison	34,804	610	21,230,440	0.021
Total, All Livestock	139,315,740.00		46,335,506,560	45.7839
Young chickens	8,536,865,000	Not reported	44,317,531,000	43.790
Mature chickens	147,569,000	Not reported	824,973,000	0.815
Young turkeys	264,753,000	Not reported	7,093,431,000	7.009
Mature turkeys	3,028,000	Not reported	81,480,000	0.081
Ducks	24,301,000	Not reported	160,871,000	0.159
Geese	215,109	Not reported	3,014,303	0.003
Other fowl (include ratites)	8,251,275	Not reported	6,253,088	0.006
Total, Poultry	8,984,982,384	•	52,487,553,391	51.8627
Rabbits	, , - ,	Not reported	1,720,481	0.002
Egg products		Not reported	2,380,132,000	2.352
GRAND TOTAL, ALL PRO	DUCTION CLASSI		101,204,912,432	100

Chart 1 2003 Consumption Data



# **DEFINITIONS OF PRODUCTION CLASSES**

Production classes are defined as follows:

- Bulls are mature, intact male cattle.
- Beef cows are sexually mature female cattle of beef type, ordinarily having given birth to one or more calves.
- Dairy cows are sexually mature female cattle of dairy type, ordinarily having given birth to one or more calves.
- Heifers are young, female cattle that have not yet given birth to a calf.
- Steers are male cattle castrated before sexual maturity.
- Calves/veal definitions are under FSIS review.
- Market hogs are swine usually marketed near six months of age and 200 to 300 pounds live weight.
- Boars are mature swine showing male sexual characteristics.
- Stags are male swine castrated after they have reached sexual maturity.
- Sows are mature female swine ordinarily having given birth to one or more litters.
- Sheep include mature sheep with no distinction by gender.
- Lambs are generally defined as sheep younger than 14 months and having a break joint in at least one leg.
- Goats are of both sex and any age.
- Horses are of either sex or any age.
- Other livestock include bison, deer, elk, etc.
- Young chickens include: broilers/fryers that are usually less than 10 weeks of age, roasting chickens are young chickens of either sex usually less than 12 weeks of age, and capons that are surgically neutered male chickens usually less than 8 months of age.
- Mature chickens are adult female chickens usually more than 10 months of age.
- Young turkeys include fryer/roaster turkeys that are either male or female and usually less than 12 weeks of age, and turkeys that are either male or female usually less than 6 months of age.
- Mature turkeys are of both sex and usually more than 15 months of age.
- Ducks are of both sex and any age.
- Geese are of both sex and any age.
- Other poultry include ratites (typically ostriches, emus and rheas), guineas, squabs (young, unfledged pigeons), adult pigeons, pheasants, grouse, partridge, quail etc.;
- Rabbits are any of several lagomorph mammals.
- Egg products are yolks, whites, or whole eggs after breaking and can be dried, frozen, or liquid.

### INTRODUCTION

The Food Safety and Inspection Service (FSIS), the U.S. Department of Agriculture's public health regulatory agency, works with the Environmental Protection Agency (EPA) and the Department of Health and Human Service's, Food and Drug Administration (FDA), to control veterinary drug, pesticide, and contaminant residues in meat, poultry, and egg products. Residue control is a cooperative effort. EPA and FDA have statutory authority for establishing residue tolerances\*, and FSIS, through the National Residue Program (NRP) tests animal tissues and egg products to verify that tolerance levels are not violated.

FDA, under the Federal Food Drug and Cosmetic Act, establishes tolerance levels for veterinary drugs, food additives, and unavoidable contaminants. EPA, through the Federal Insecticide, Fungicide and Rodenticide Act (as modified by the Food Quality Protection Act), sets tolerance levels for registered pesticides. For cancelled pesticides, action levels (similar to tolerances, but less formal) are established by FDA or FSIS, based on recommendations that EPA published in the Federal Register. FDA and EPA also have the authority to ensure compliance with established tolerance levels.

FSIS protects consumers from chemical residues by analyzing meat, poultry, and egg products, and by preventing product adulterated with chemical residues from entering the food supply. This authority is provided under the Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Egg Products Inspection Act. FSIS regulations are published in Title 9 of the Code of Federal Regulations (9 CFR), chapter III.

Since 1967, FSIS has administered the NRP to collect data on chemical residues in domestic and imported meat, poultry, and egg products. The NRP is designed to provide: (1) a structured process for identifying and evaluating compounds of concern by production class; (2) the capability to analyze for compounds of concern; (3) appropriate regulatory follow-up of reports of violative tissue residues; and (4) collection, statistical analysis, and reporting of the results of these activities.

With the implementation of the Hazard Analysis and Critical Control Points (HACCP) inspection system, another important component of the NRP is to provide verification of residue control in HACCP systems. As part of the HACCP regulation, slaughter and production establishments are required for identifying all chemical residue hazards that are reasonably likely to occur, and develop systems to guard against them. A vigilant chemical residue prevention program is essential to foster the prudent use of drugs and pesticides in food animals. In 1999, the NRP was modified to make residue evaluation more consistent with risk assessment principals.

The NRP includes a variety of sampling plans to prevent violative residues from entering the food supply. The range of chemical compounds evaluated for inclusion in the various NRP sampling plans is comprehensive. It includes approved and unapproved veterinary drugs and pesticides known or suspected to be present in domestic food animals and egg products or in countries exporting products to the U.S. It also includes any other xenobiotic or naturally

occurring compounds that may appear in meat, poultry, and egg products and may pose a potential human health hazard.

A violation in a production class (food animal or egg product) occurs when a chemical residue is found and the residue is in excess of an established tolerance. When a violative chemical residue is detected in an animal presented for slaughter or in an egg product, FSIS condemns the adulterated product. If the product has been distributed into commerce, it is subject to a voluntary recall. FSIS notifies FDA of the violation and assists in obtaining the names of producers and, in the case of food animal products, other parties involved in offering the animals for sale. FDA and cooperating state agencies follow-up with on-site visits to these firms for an educational visit.

If a problem is not corrected, subsequent FDA visits could result in enforcement action, including prosecution. FSIS posts a Repeat Violator List on the agency web site, listing the names and addresses of parties FDA has determined are responsible for more than one drug, pesticide, or other chemical residue violation in a 12-month period. The list provides information helpful to processors and producers working to avoid residue contamination and serves as a deterrent for violators, while enabling FSIS to make better use of resources.

Data gathered in the NRP is used to verify the safety of meat, poultry, and egg products in the United States. The program assists FSIS, FDA, and EPA to enforce Federal laws and regulations, and assists the agencies to design programs to enhance the nation's residue control programs.

<sup>\*</sup>Tolerance levels established by FDA are published in 21 CFR.

Tolerance levels established by EPA are published in Title 40 CFR.

# COMPONENTS OF THE NATIONAL RESIDUE PROGRAM

The NRP is comprised of sampling plans to address chemical and veterinary drug residues in domestic and imported food animals and egg products. All products, whether domestic or imported, must fall within the tolerance levels set by FDA and EPA.

#### DOMESTIC SAMPLING PLAN

The domestic sampling plan ensures that egg products and products from food producing animals in the United States comply with residue regulations. Sampling of meat, poultry and egg products also verifies that Hazard Analysis and Critical Control Points (HACCP) systems address residue control.

There are four components of the domestic residue sampling plan: Monitoring, Enforcement, Surveillance, and Exploratory sampling. FSIS enters sampling results into the Microbiological and Residue Computer Information System (MARCIS). Data in MARCIS are used to develop future residue testing programs; create educational information for food producers; and provide agencies with information needed to take appropriate action on sample results.

# **Monitoring**

Monitoring samples provides information on the prevalence of chemical residues in domestic food animals and egg products. FSIS schedules inspectors to collect tissue samples from randomly selected food animals that have passed ante- and post-mortem inspections, or from egg products that have passed inspection. Products are not retained pending laboratory analysis. If results indicate a potential public health concern, products may be subject to recall.

Data obtained by monitoring sampling are used to evaluate residue trends. For example, if data indicate a compound is being abused, a targeted sampling program may be instituted.

#### **Enforcement**

Enforcement sampling is conducted when an inspector identifies a specific animal as suspect for residue violations. An inspector may deem an animal suspect because of historical information on a production class, or based on ante- and post-mortem inspections.

FSIS inspectors can screen samples for the presence of antibiotics or sulfonamides using two in-plant tests:

- The Swab Test on Premises (STOP) is validated for use in all production classes to detect the presence of antibiotic and sulfonamide drug residues in kidney tissues; and
- The Fast Antimicrobial Screen Test (FAST) is validated for use in bovine to detect the presence of antibiotic and sulfonamide drug residues in kidney tissues.

When an in-plant screen test detects a positive sample, a confirmation test is conducted at an FSIS laboratory. If an in-plant test is not available, or if the presence of a chemical residue that cannot be detected by STOP or FAST is suspected, the appropriate tissue samples are sent directly to the FSIS laboratory. Carcasses sampled for enforcement testing are retained pending laboratory results. If a violative level is found, the carcass is deemed adulterated and is condemned.

#### Surveillance

Surveillance sampling is scheduled based on a regulation or agency policy implemented to address residue concerns in a specific population. Data collected by surveillance sampling measures the extent of a chemical residue problem in a suspect population or product. Data are periodically evaluated to determine whether interventions have led to a reduction in the occurrence of residues. Depending on the weight of evidence that led to testing, sampled carcasses may or may not be held pending laboratory results.

# **Exploratory**

Exploratory sampling studies the occurrence of residues for which no tolerance has been established; evaluates new methods and approaches for monitoring sampling; and provides information to supplement the monitoring program. Exploratory sampling is for information gathering, and regulatory action is not taken based on the analyzed samples.

#### IMPORT SAMPLING PLAN

Animal and egg products imported to the U.S. have passed inspection in their country; therefore, import sampling is reinspection. The levels of reinspection are:

- Normal sampling, which is defined as random sampling from a lot;
- Increased sampling, which is defined as above the normal sampling as the result of an Agency management decision; and
- Intensified sampling, which is defined as occurring when a previous sample for a type of inspection failed to meet U.S. requirements.

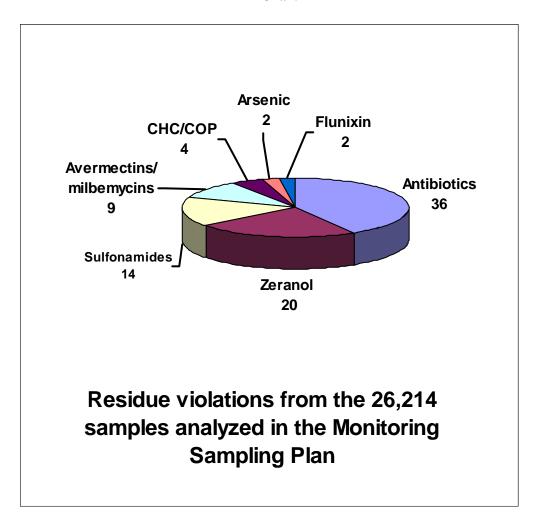
For both normal and increased sampling, the lot is not required to be retained pending laboratory results; however, the importer may retain the lot pending the laboratory results. For intensified sampling, the lot must be held pending laboratory results. The level of reinspection that is applied depends on the country's performance history. The data obtained from laboratory analysis are entered into an FSIS Data Base System, the Automated Import Information System (AIIS). Import sampling is designed to verify that the equivalence of chemical residue programs in countries exporting meat, poultry, and egg products to the U.S. are equivalent to those in the U.S.

# SUMMARY OF DOMESTIC DATA

# **MONITORING**

Twelve (12) compound classes of veterinary drugs and pesticides comprised of approximately 59 residues were analyzed. Of the 26,214 samples analyzed in 2003, 87 residue violations were found. The residue violations consisted (see Chart 2) of 36 antibiotics, 20 zeranol, 14 sulfonamides, 9 avermectins/milbemycins, 4 chlorinated hydrocarbon/chlorinated organophosphate, 2 arsenics, and 2 flunixin. There were no residue violations in the testing of chloramphenicol, ractopamine, beta-agonists, melengestrol acetate, and diethylstilbestrol.

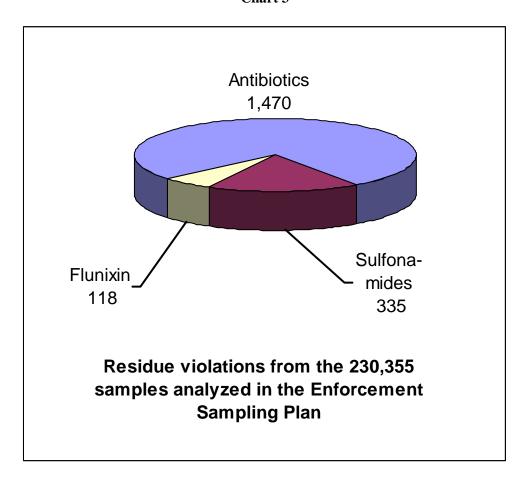
Chart 2



# **ENFORCEMENT**

Seven (7) compound classes of veterinary drugs comprising approximately 14 residues were analyzed. Of the 230,351 samples analyzed in 2003, 1,923 residue violations were found. The residue violations consisted (see Chart 3) of 1,470 antibiotics, 118 flunixin, and 335 sulfonamides. No violations were found in the testing for arsenicals, chloramphenicol, diethylstilbestrol, and zeranol.

Chart 3



# **SURVEILLANCE**

**Market Hogs -** 6,295 market hogs were screened for sulfonamides using the Sulfa-On-Site test (SOS). There were 10 violations, all for the residue sulfamethazine.

**Bob Veal** - 38, 959 bob veal were screened for antibiotics and sulfonamides using the Fast Antimicrobial Screen Test (FAST). The total bob veal tested includes both surveillance sampling (testing of a suspect population) and enforcement sampling (testing of suspect animals). Of the animals tested, 481 laboratory confirmed violations were found in 443 animals. The residue violations consisted of 372 neomycin, 35 penicillin, 26 sulfamethazine, 22 gentamicin, 15 oxytetracycline, 13 sulfadimethoxine, 3 sulfamethoxazole, 2 tylosin, 2 tetracycline, and 1 tilmicosin.

**Show Animals** – Ten (10) show animals were tested. Five animals were tested for ractopamine (1 steer, heifer, and market hog, and 2 lambs.) Five animals were tested for antibiotics and sulfonamides (1 market hog and 4 lambs.) No violations were found.

#### **EXPLORATORY**

Exploratory sampling for lead and cadmium was implemented in October 2003. Twenty seven (27) heifers and 19 dairy cows were tested in 2003. The data collected during 2003 will be reported with the results collected in 2004.

# COMPARSION OF NUMBER OF TESTS PERFORMED UNDER MONITORING, ENFORCEMENT, AND SURVEILLANCE

#### **COMPARSION BY PRODUCTION CLASS**

Table 2, *Comparsion by Production Class*, presents the number of animals tested under monitoring, enforcement and surveillance sampling for each production class.

Table 2 Comparison by Production Class 2003 Domestic Sampling Plan

<b>Production Class</b>	Number of Tests under Monitoring	Number of Tests under Enforcement	Number of Tests under Surveillance
Horses	698	117	
Bovine		10,586	
Bulls	1,129	1,292	
Steers	1,533	5,624	1
Beef cows	1,610	14,668	
Heifers	1,415	3,009	1
Dairy cows	1,043	150,100	
Bob veal	953	38,959¹	
Formula-fed veal	1,667	569	
Non-formula-fed veal	735	141	
Heavy calves	962	694	
Calves		1	
Mature sheep	479	43	
Lambs	986	367	6
Goats	1,254	111	
Porcine		2	_

The total analyzed includes both surveillance testing (testing of a suspect population) and enforcement testing (testing of suspect animals)

# Table 2 – continued Comparison by Production Class 2003 Domestic Sampling Plan

Production Class	Number of Tests under Monitoring	Number of Tests under Enforcement	Number of Tests under Surveillance
Market hogs	1,802	3,239	2
Boars/Stags	1,146	57	
Sows	1,360	643	
Roaster pigs	92	1	
Bison	33		
Chickens		6	
Young chickens	2,245	2	
Mature chickens	751		
Turkeys		3	
Young turkeys	1,303	16	
Mature turkeys	755		
Ducks	926		
Geese	58		
Squab	63		
Ratites	35		
Rabbits	125		
Egg products	1,056		
Other		101	
Total	26,214	230,351	6,305

# **COMPARSION BY COMPOUND CLASS**

Table 3, *Comparison by Compound Class*, presents the number of tests performed under monitoring, enforcement and surveillance sampling for each compound class.

Table 3 Comparison by Compound Class 2003 Domestic Sampling Plan

Compound Class	Number of Tests under Monitoring	Number of Tests under Enforcement	Number of Tests under Surveillance
Antibiotics	5,608		
Antibiotics and sulfonamides		230,315	
Sulfonamides	5,276		
Arsenic	3,825	3	
CHCs/COPs/Phenylbutazone	5,962		
Avermectins/Milbemycins	3,495		
Chloramphenicol	633	19	
Melengestrol acetate	187		
Beta-agonists	304		
Ractopamine	324		
Flunixin	202	1	
DES/Zeranol	398	13	
Total	26,214	230,351	6,305

# SUMMARY OF IMPORT DATA

The United States imported approximately 3,858,822,771 pounds of fresh and processed meat, poultry, and egg product from 23 countries. The testing program included 8 compound classes of veterinary drugs and pesticides, comprising approximately 50 residues. Two (2) violations were found out of the 2,212 reported results.

#### **NORMAL**

Eight (8) compound classes of veterinary drugs and pesticides, comprising approximately 50 residues were analyzed. Of the 2,099 samples analyzed, 1 violation was found in a fresh meat product.

# **INCREASED**

Six (6) compound classes of veterinary drugs and pesticides, comprising approximately 50 residues were analyzed. Twenty (20) samples were analyzed and no violations were found.

# **INTENSIFIED**

Seven (7) compound classes of veterinary drugs and pesticides, comprising approximately 50 residues were analyzed. Ninety-three (93) samples were analyzed and one violation was found in a fresh meat product.